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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,313	04/09/2002	Sharon May Armitage	1386/5 PCT	7941

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,313	ARMITAGE ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/22/03; 11/25/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>1103</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>0202; 0302</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed September 22, 2003 and November 25, 2003. Currently, claims 33-47 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group I in the paper filed September 22, 2003 is acknowledged.

The claims filed in response to the restriction requirement did not appear to correspond to the pending claims in the application. The pending claims were the amended claims filed in the 371 application. The applicant appeared to have been working from the originally filed claims. Following a telephonic interview with Michael Krawzsenek, applicant filed a complete set of pending claims drawn only to a single group, namely a device.

Priority

3. This application is a 371 application of PCT/AU00/01039, filed September 1, 2000 and claims priority to foreign filed Australia PQ 2658, filed September 3, 1999.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

4. The drawings are acceptable.

Specification

5. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

6. Claim 42 is objected to because the claim depends upon itself. The claim has been interpreted to depend on Claim 33, from which most of the other claims depend. Appropriate correction is required.

7. Claims 44-46 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 44-46 are directed to intended uses and method step which do not add any limitations to a product device. For example, Claim 44 does not add any limitations to the device of Claim 33 by indicating that a hole punch takes a portion of the sample. Claims 45-46 are directed to the method of digesting a sample and further analyzing a sample. These limitations also fail to limit the product device in any manner.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 33-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 33-47 are indefinite over the recitation "said sample" in claims 33, 44-46 because Claim 33 sets forth a biological sample. The claims may be easily amended to recited "said biological sample" to make it clear that said sample is referring to the biological sample.

B) Claim 34-35 are indefinite over the recitation "suitable for digestion together with said biological sample" because it is unclear whether "sheets of material are digestable with the sample" to form a solution or whether the "sheets of material allow a sample to be digested" or whether the "sheets of material" allow for a sample to be eluted and/or obtained. Further, from the specification, it does not appear that the sheets of material are digested with the biological sample. According to Example 1, a hole is punched through a sample storage device and placed in a tube or well, centrifuged to collect the sub-sample in the bottom of the tube. The supernatant is transferred to a tube for amplification and analysis. It is unclear from the example whether the paper or polypropylene film would be digested at these conditions or whether the sample is merely eluted from the storage means. Thus, the metes and bounds of the claimed invention are unclear.

C) Claim 35 is indefinite over the recitation "substantially irreversibly adhered together" because it is unclear what is within the scope of the recitation. The term "substantially irreversibly adhered together" in claim 35 is a relative term which renders the claim indefinite. The term "substantially irreversibly adhered together" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

D) Claim 36 is indefinite over the recitation "said base sheet." Claim 33 fails to provide a base sheet. Thus, "said base sheet" lacks antecedent basis.

E) Claim 37 is indefinite over the recitation "the cover sheet." Claim 33 fails to provide a cover sheet. Thus, "the cover sheet" lacks antecedent basis.

F) Claim 38 is indefinite over the recitation "the base sheet." Claim 33 fails to provide a base sheet. Thus, "the base sheet" lacks antecedent basis.

G) Claim 39 is indefinite over the recitation "the cover sheet." Claim 33 or 38 fails to provide a cover sheet. Thus, "the cover sheet" lacks antecedent basis.

H) Claim 40 is indefinite over the recitation "the cover sheet." Claim 33 fails to provide a cover sheet. Thus, "the cover sheet" lacks antecedent basis.

I) Claim 41 is indefinite over the recitation "the backing sheet." Claim 33 fails to provide a backing sheet. Thus, "the backing sheet" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 33-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Perlman (US Pat. 5,858,770, January 12, 1999).

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Where means plus function language is used to define the characteristics of a machine or manufacture invention, claim limitations must be interpreted to read on only

the structures or materials disclosed in the specification and "equivalents thereof." (Two en banc decisions of the Federal Circuit have made clear that the Office is to interpret means plus function language according to 35 U.S.C. 112, sixth paragraph. The instant specification defines a storage means on page 4 of the specification as comprising a base sheet, a cover sheet and a backing sheet (see page 4 for complete storage means). With respect to the claims requiring "material suitable for digestion together with said biological sample," the claims have been broadly interpreted to mean that the sample is eluted or obtained from the material, see the 112/2nd rejection above.

Perlman teaches a cell culture plate with oxygen and carbon dioxide-permeable waterproof sealing membrane. Perlman teaches a cell culture plate which is covered and sealed with a waterproof adhesive sealing membrane (abstract). Perlman teaches that the prior art uses a cover which may be a gas-impermeable adhesive polyester, polypropylene or polyethylene plastic sealing film (col. 1, lines 50-51)(limitations of Claim 33, 40).

With respect to the invention of Perlman, Perlman improving the multiwell culture plate by providing a gas-permeable, leak-proof, and adhesive membrane for sealing such plates. Perlman teaches that membranes are generally thin, and is does not peel off any of the culture plates tested (col. 2, lines 13-14). The membranes of Perlman are polyester-polyurethane or polyether-polyurethnae which adhere to the culture plate to exclude contaminants from the wells of the plate (col. 3, lines 20-30). The removable release sheet may be attached to the lower surface or adhesive coating on the facestock to protect the adhesive from contaminating substances prior to use (col. 4,

lines 55-60). As shown in Figure 1, a cell culture plate is assembled from a sterile sheet assembly and a cell culture plate (limitations of Claim 33-35, 43, 47). The sheet assembly consist of three layers, an upper layer which serves as a carrier sheet, a middle layer which functions as the breathable adhesive sealing membrane and a lower layer which functions as a release paper sheet to protect the adhesive coating (col. 7, lines 5-12)(limitations of Claim 37, 39, 41). With respect to Claims 44-47, the claims are drawn to intended use or method steps which fail to add any particular limitations to the device. Thus, these limitations fail to distinguish the device from the structure of the prior art device. Since, Perlman teaches every limitation of the claims, Perlman anticipates the claimed invention.

10. Claims 33-39, 41-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiersteiner (US Pat. 3,733,025, May 1973).

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danyl*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Where means plus function language is used to define the characteristics of a machine or manufacture invention, claim limitations must be interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof." (Two en banc decisions of the Federal Circuit have made clear that the Office is to interpret means plus function language according to 35 U.S.C. 112, sixth paragraph. The instant specification defines a storage means on page 4 of the specification as comprising a base sheet, a cover sheet and a backing sheet (see page 4 for complete storage means). With respect to the claims requiring "material suitable for digestion together with said biological sample," the claims have been broadly interpreted to mean that the sample is eluted or obtained from the material, see the 112/2nd rejection above.

Hiersteiner teaches an easy opening envelope, a device, which comprises a tamper-evident storage means for storing a sample. As seen in Figure 1, the envelope comprises a backing sheet which is releasably secured to the surface of the cover sheet facing the base sheet (Figure 1, number 22)(limitations of Claim 41). An adhesive strip is applied over the exposed surface which is releasable type (col. 2, lines 8-10). The adhesive strip is permanently affixed to the cover sheet (limitations of Claim 39, 47). The envelope also comprises a base sheet where the biological sample may be placed and a cover sheet which is secured to the base sheet through a fold line (see Figure 1, number 19)(limitations of Claim 37, 43). To open the envelope the cover may be torn from the base sheet using number 31, with tear perforations which would illustrate that the product had been tampered with, i.e. tamper evident. The sheets are substantially irreversibly adhered together (limitations of Claim 35). Hiersteiner teaches that the

envelope is made of paper (col. 2, lines 19-20)(limitations of Claim 38). Paper is suitable for digestion (limitations of Claim 34). Since the envelope is used for mailing items in the pocket, addresses and stamps are placed on the reverse side of the base sheet (limitation of Claim 36). With respect to Claims 44-47, the claims are drawn to intended use or method steps which fail to add any particular limitations to the device. Thus, these limitations fail to distinguish the device from the structure of the prior art device. Since, Hiersteiner teaches every limitation of the claims, Hiersteiner anticipates the claimed invention.

11. Claims 33-35, 41, 43-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Bender (US Pat 3,965,888, June 1976).

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Where means plus function language is used to define the characteristics of a machine or manufacture invention, claim limitations must be interpreted to read on only

the structures or materials disclosed in the specification and “equivalents thereof.” (Two en banc decisions of the Federal Circuit have made clear that the Office is to interpret means plus function language according to 35 U.S.C. 112, sixth paragraph. The instant specification defines a storage means on page 4 of the specification as comprising a base sheet, a cover sheet and a backing sheet (see page 4 for complete storage means). With respect to the claims requiring “material suitable for digestion together with said biological sample,” the claims have been broadly interpreted to mean that the sample is eluted or obtained from the material, see the 112/2nd rejection above.

Bender teaches a specimen collector and holder. The specimen holder includes a transparent adhesive coated foldable segment that is used to collect the specimen and retain the back-folded segment for visual examination (abstract). As seen in Figure 1, the collector contains a base, a cover and a releasable adhered backing sheet (limitations of Claim 33-34, 43, 47). After a sample is collected, the adhesive segment is folded-back for visualization. The collector of Bender allows specimen transfers and the use of glass slides are eliminated while the specimen can be conveniently examined without contamination. The transparent plastic material segment is provided with a fold-line located in such manner that the adhesive area may be folded back upon the main body of the swab itself so that the specimen can be examined through the transparent swab (col. 1, lines 55-65). Prior to use of the swab, the cover sheet (number 18) is removed and the adhesive is then applied to a body surface (col. 3, lines 5-10)(limitations of Claim 35, 41). After collection of the specimen by its sticking to the adhesive the end is bent back upon itself so that the adhesive segment is located

against the transparent flat area of the swab (col. 3, lines 10-15). The specimen can then be examined through the transparent swab while being protected (col. 3, lines 15-20). With respect to Claims 44-47, the claims are drawn to intended use or method steps which fail to add any particular limitations to the device. Thus, these limitations fail to distinguish the device from the structure of the prior art device. Since Bender teaches each limitation of the instant claims, Bender anticipates the instant invention.

12. Claims 33-35, 37-39, 43-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Draper (US Pat. 6,007,104, December 1999).

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danyl*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Where means plus function language is used to define the characteristics of a machine or manufacture invention, claim limitations must be interpreted to read on only the structures or materials disclosed in the specification and “equivalents thereof.” (Two en banc decisions of the Federal Circuit have made clear that the Office is to interpret

means plus function language according to 35 U.S.C. 112, sixth paragraph. The instant specification defines a storage means on page 4 of the specification as comprising a base sheet, a cover sheet and a backing sheet (see page 4 for complete storage means). With respect to the claims requiring "material suitable for digestion together with said biological sample," the claims have been broadly interpreted to mean that the sample is eluted or obtained from the material, see the 112/2nd rejection above.

Draper teaches a medical device and form for collecting samples. The device, as seen in Figure 1-3 illustrates a multilayer device for collecting laboratory samples. On the left side of the device, samples are obtained and on the right side of the device, information including individual, insurance information is included along with bar codes. The separation line divides the form portion from the medical device portion. A securement sheet has a pressure sensitive adhesive which secures the medical device to the substrate (col. 2, lines 25-30). The device, as seen in Figure 3, contains a base sheet, a cover sheet with an adhesive (limitations of Claim 33-35, 37, 43). The substrate is a heavyweight paper or paperboard (col. 3, lines 15-20). The form portion contains biographical data, instructions, bar codes and other identification material (col. 3, lines 15-20). A blood application sheet is secured to the front of the substrate by a securement sheet. The securement sheet includes a pressure sensitive adhesive (col. 4, lines 15-25)(limitations of Claim 39). The back cover sheet is preferably a flexible sheet of water, oil and grease resistant paper (col. 4, lines 55-60)(limitations of Claim 38). With respect to Claims 44-47, the claims are drawn to intended use or method steps which fail to add any particular limitations to the device. Thus, these limitations fail

to distinguish the device from the structure of the prior art device. Since Draper teaches every limitation of the instant claims, Draper anticipates the claimed invention.

Conclusion

13. No claims allowable over the art.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A) Cleveland et al (US Pat. 2002/0123061, September 5, 2002) teaches a method of collecting genetic material on a storage card, placing the storage card in "zip-lock" bag and placing the bag in an envelope.

B) Staub et al. (US Pat 6,187,540, February 2001) teaches a hinges or bifold sheet which is made of paper and allows collection of samples. The device is a tamper-proof device.

C) Turner (US Pat. 5,211,286, May 1993) teaches a personal identification system which places hair, blood, fingerprint samples in plastic bags and into a case for storage.

D) Ota et al. (US Pat. 5,336,162, August 1994) teaches a medical bandage with plastic adhesive tape stuck to the butting part.

E) Sorrell (US Pat. 3,675,844, July 1972) teaches an envelope with sealing means.

F) Chung et al. (US Pat. 6,355,439, March 2002) teaches a method for obtaining DNA for analysis by taking epidermis by means of an adhesive sheet.


G) Ushiyama et al. (US Publication 2002/0192742, December 2002) teaches a microorganism incubator and culture medium which comprises a water soluble polymer layer laminated with a matrix layer.

H) Elliott et al. (US Pat 6,607,699, August 2003) teaches a hair root collection kit which comprises a care with an adhesive strip extending across the holder.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m. After January 13, 2003, the examiner's phone number will be 571-272-0743.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
Patent Examiner
December 11, 2003